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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------------|------------------|
| 09/677,574 | 10/03/2000 | Shuwei Yang | 0942.4500004/RWE/BJD | 1982 |
| 26111 | 7590 | 07/28/2004 | | |
| STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005 | | | EXAMINER HUTSON, RICHARD G | |
| | | | ART UNIT | PAPER NUMBER |

1652

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 09/677,574 | Applicant(s) YANG ET AL. | |
| | Examiner Richard G Hutson | Art Unit 1652 | |

**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-9,14,17,20,37-40,47,50-54,57,59,61,64-69,71-76 and 78-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-9,14,17,20,37-40,47,50-54,57,59,61,64-69,71-76 and 78-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendment of claims 1, 2, 4, 5, 14, 17, 20, 47, 50, 57, 61, 71, 78-80 cancellation of claims 10-13, 15, 16, 18, 19, 21-36, 41-46, 48, 49, 55, 56, 58, 62, 63, 70 and 77, Paper of 5/4/2004, is acknowledged.

Claims 1, 2, 4-9, 14, 17, 20, 37-40, 47, 50-54, 57, 59, 61, 64-69, 71-76 and 78-82 are still at issue and are present for examination.

Applicants' arguments filed on 5/4/2004, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-9, 14, 17, 20, 37-40, 47, 50-54, 57, 59, 61, 64-69, 71-76, 78-82, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was stated in the previous office actions of 4/23/2002, 4/29/2003 and 12/4/2003 as it applied to the previous claims. In response to this rejection,

applicants have amended the claims and continue to traverse this rejection as it applies to the newly amended claims.

The newly amended claims are directed to all possible Pol I type DNA polymerases which have been modified or mutated at a position corresponding to Arg 722, Lys 726 or both Arg 722 and Lys 726 of a *Thermotoga neopolitana* polymerase and kits comprising said modified polymerases.

Applicants have amended the above rejected claims such that they are no longer drawn to any nucleic acid polymerase to any Pol I type DNA polymerase and continue to traverse the rejection given this amendment.

Applicants continue to submit that relative to biotechnology inventions, the Federal Circuit has instructed that functional descriptions of biological material can satisfy the written description requirement if a structure / function correlation is known in the art. Applicants submit that they have provided numerous examples, subspecies and specific examples that could serve as a backbone for making the recited substitutions of the invention and that in addition the skill and knowledge in the art regarding Pol I type DNA polymerases and their domain structure at the time of filing is substantial. This includes the knowledge of the domain structure, as well as specific mutations of these domains. Applicants additionally continue to point out that the specific mutations of claimed Pol I type DNA polymerase are all within the O-helix region, which typically defines the nucleotide binding domain of the DNA polymerases.

Applicants argument in full is acknowledged, however, continues to be found not persuasive for the reasons previously made of record. Further applicants are reminded

that the current rejection is based on a lack of written description, not a lack of enablement, and while enablement is related to the description of the invention, the rejections are different and while applicants may have enabled the current claims they have not adequately described the current claimed genus of any Pol I type DNA polymerase having the specifically claimed mutations.

There is no disclosure of any particular structure to function/activity relationship for the claimed genus that of any Pol I type DNA polymerase, as discussed previously and above. Given the lack of species representative of the claimed genus, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

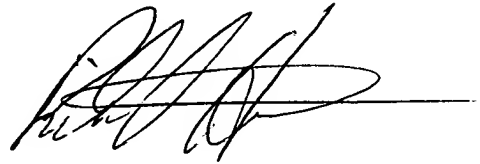
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax

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phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a long horizontal line extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rg
7/23/2004